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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/732,988      | 12/10/2003  | Masayuki Nakamura    | 671303-2001         | 8499             |

20999 7590 02/17/2005

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EXAMINER

HUANG, EVELYN MEI

|          |              |
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| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/732,988

**Applicant(s)**

NAKAMURA ET AL.

**Examiner**

Evelyn Huang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-9 are pending.

#### ***Election/Restrictions***

2. In response to the restriction requirement mailed on 11-16-2004, Applicants have elected with traverse the invention of Group I, claims 1-8. Group II is withdrawn from consideration as being drawn to the non-elected invention.

Applicant argues that all the different diseases of Group II are mediated by the a metabotropic glutamic acid receptor, and it would not be a burden for the examiner to search Group II together with Group I.

On the contrary, compounds falling within the instantly claimed genus are known to have utility other the disclosed conditions mediated by a metabotropic glutamic acid receptor, such as useful as hypolipidemic agents (Nadelson, 4049813). A reference (such as Nadelson, 4049813) anticipating the Group I invention would not render obvious the Group II invention. The search is not co-extensive and is burdensome. The restriction as indicated is therefore proper.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 1-8, the term 'derivatives' is open-ended and is therefore indefinite. Replacing it with 'compound' is recommended.
- b. Claims 1-8, it is unclear whether these claims are directed to a mixture of compounds or pharmaceutically acceptable salts thereof or to a compound or a

pharmaceutically acceptable salt thereof. It is recommended the compound claims be amended to the singular/alternative format, i.e. A compound of formula ....or a pharmaceutically acceptable salt thereof.

c. The term 'heteroaryl' without the specification of the size, the number and kind of heteroatoms and the number of rings is unclear. It is recommended that the definition be recited in the claims.

The term 'substituted' without recitation of the substituents in the claims is indefinite as it embraces substituents not described or known at the time of the invention.

Although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims. In re Van Guens, 26 USPQ2d 1057. Recitation of these critical limitations in the claims is required for distinctly claiming the subject matter which the applicant regards as his invention.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Denzer (4113727). The compound of Example 4 (column 6) and the compounds (m), (r), (s), (t) (column 8), are encompassed by the instant claim.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nadelson I (4064251). The compounds of Example 3a, 3b (column 8) are encompassed by the instant claim.

7. Claims 1, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Nadelson II (4049813). The compounds a-e of Example 4 (column 9, lines 30-40), and the compounds a-i of

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Example 5, are encompassed by the instant claim 1. Compound c of Example 4 and compound c of Example 5 having 3-(p-anisyl) (i.e. 4-methoxyphenyl) are encompassed by instant claim 5.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (4113727).

Denzer generically discloses a substituted isoxazolo[4,5-c]pyridine-4-(5H)-ones useful as a hypolipidemic agent (column 1). A specific compound is described (column 6, Example 4).

Denzer's Example 4 has a hydrogen whereas the compound of instant claim 6 has a methoxy on the R1a phenyl.

Denzer, however, teaches that hydrogen and methoxy are optional substituents on the phenyl (column 1, definition of R4, lines 34-40). Methoxy is exemplified in Example 2, compound (d).

At the time of the invention, one of ordinary skill in the art would be motivated to replace the hydrogen with the alternative methoxy as taught by Denzer to arrive at the instant invention with the reasonable expectation of obtaining an additional hypolipidemic compound, for Denzer had clearly taught that any species within the disclosed genus would be useful as a hypolipidemic agent.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Furthermore, the instant is a CIP of PCT/JP/05898, which is published in Japanese, the examiner is not able to determine the subject matter that does not have support in the priority documents.

Claims 1, 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Hintermann (WO 2003015780, filed on 8-14-2002, which is before the instant filing date of 12-10-2003). The compounds of Examples 1, 3, 5-8 (pages 9-10) and the compound of claim 4 are encompassed by the instant claim 1. The compound of Example 2 is encompassed by the instant claims 1, 8.

### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Furthermore, the instant is a CIP of PCT/JP/05898, which is published in Japanese, the examiner is not able to determine the subject matter that does not have support in the priority documents.

Claims 1, 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Hintermann (WO 2003015780, published on 2-27-2003, which is before the instant filing date of 12-10-2003). The

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compounds of Examples 1, 3, 5-8 (pages 9-10) and the compound of claim 4 are encompassed by the instant claim 1. The compound of Example 2 is encompassed by the instant claims 1, 8.

*Allowable Subject Matter*

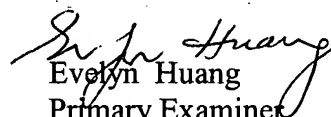
11. The compound wherein R1a is pyridyl would be allowable upon overcoming the 112 second paragraph rejection.

Denzer (4113727), Nadelson I (4064251) or II (4049813) only teaches phenyl as R1a. Lacking is the motivation to replace the prior art phenyl with a pyridyl to arrive at the instant invention.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625